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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,049	01/31/2001	Hal S. Padgett	P-LG 4412	3170

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/26/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,049

Applicant(s)

PADGETT ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/19/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 32 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,13,22,23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,11,12,14-21,24,25 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 1/31/2001 (original) is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-26 and 32 and species polynucleotides only (claims 2-8, 11, 12, 15-21, 24, 25, and 32) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "claim 27 or 28" in the claim. There is insufficient antecedent basis for this limitation in the claim since claims 27 and 28 were canceled by applicant.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8, 11, 14-21, 24, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crameri *et al.*, (US Patent No. 6,319,714, Priority date is January 1999) as evidence by Stemmer *et al.*, (US Patent No. 5,830, 721, published on November 3, 1998) in view of Wong *et al.*, (US Patent No. 4,910,141, published on March 20, 1990).

Crameri *et al.*, teach oligonucleotide mediated nucleic acid recombination by shuffling. First, sets of overlapping family gene (double stranded DNA) were digested with DNase I as recited in claims 11 and 24 and digested DNA fragment were denatured and reannealed in the presence of bridging oligonucleotides or incorporated oligonucleotides. Then these DNA

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fragments and oligonucleotides were used for PCR (including denaturation, annealing, and extension steps) in the absence and presence of primers to generate recombinant DNA (see US Patent No. No.5,830, 721, Example 1 in columns 38-40). Any or all of these above steps could be repeated reiteratively as recited in claims 3, 4, 16, and 17 to provide for multiple recombination and selection events to produce a nucleic acid with a desired trait or property (see Figure 1 and columns 2-4, 39, 40, and 51-54). Note that: (1) although Crameri *et al.*, did not specify how many overlapping family genes were used in the assay, it was obvious to use 2-4 genes as recited in claims 1, 2, 5, 14, 15, and 17 in the assay (four different genes were shown in Figure 1); (2) PCR products were considered to be larger than fragments generated from DNase I digestion as recited in claims 4 and 17; (3) the step to select a nucleic acids with desired trait or property for another run of DNA shuffling was considered as isolating a size range of double stranded polynucleotides as recited in claims 6 and 19; and (4) step (f) in claims 1 and 14 was considered as the extension step in the absence of primers and claims 7, 8, and 19-21 were considered as the extension step in the presence of primers.

Crameri *et al.*, did not disclose to fragment single stranded polynucleotides as recited in claims 1 and 14. Instead, they teach to fragment double stranded polynucleotides and denature the double stranded polynucleotides to single stranded polynucleotides (see above).

Wong *et al.*, teach to digest a single stranded DNA with DNase I (see column 28, last paragraph).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have

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digested single stranded polynucleotides with DNase I in view of the prior art of Crameri *et al.*, and Wong *et al.*. One having ordinary skill in the art would have been motivated to modify the method of Crameri *et al.*, because the simple replacement of one well known method (ie., using double stranded DNA as a starting material) from another well known method (ie., using single stranded DNA as a starting material) for preparing single stranded DNA fragments would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

6. Claims 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crameri *et al.*, (US Patent No. 6,319,714, Priority date is January 1999) as evidenced by Stemmer *et al.*, (US Patent No. 5,830, 721, published on November 3, 1998) in view of Wong *et al.*, (US Patent No. 4,910,141, published on March 20, 1990) as applied to claims 1-8, 11, 14-21, 24, and 32 above, and further in view of Anderson *et al.*, (US Patent No. 5,837,860, published on November 17, 1998).

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The teachings of Crameri *et al.*, and Wong *et al.*, have been summarized previously, *supra*.

Crameri *et al.*, Stemmer *et al.*, and Wong *et al.*, do not disclose to generate single stranded polynucleotide using asymmetric PCR as recited in claims 12 and 25.

Anderson *et al.*, do teach to generate single stranded polynucleotide using asymmetric PCR.

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have generated single stranded polynucleotide using asymmetric PCR in view of the prior art of Crameri *et al.*, Wong *et al.*, and Anderson *et al.*. One having ordinary skill in the art would have been motivated to modify the methods of Crameri *et al.*, and Wong *et al.*, because the simple replacement of one well known method (ie., the method of Wong *et al.*,) from another well known method (ie., asymmetric PCR) for generating single stranded polynucleotide would have been, in the absence of an unexpected result, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

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Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

7 No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

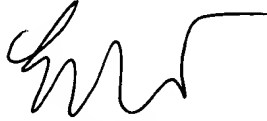
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Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 20, 2002



ETHAN C. WHISENANT
PRIMARY EXAMINER